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Evaluating the feasibility of an intervention to support smoking cessation and prevent relapse after a smokefree mental health inpatient stay

Submission date
24/10/2023

Recruitment status
No longer recruiting

Registration date
17/11/2023

Overall study status
Completed

Last Edited
20/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The proportion of people with mental illness who smoke tobacco is very high compared to the general population. It can reach figures over 70% among those in certain subgroups, such as hospitalised patients with mental illness compared to 15% in the general population. As people with mental illness are usually heavily addicted to tobacco, smoking causes large amounts of disease and deaths in this group, often from cardiovascular, respiratory illness and cancer. Smoking has been recognised as the single largest cause of health inequalities for people with mental illness. People with mental illness lose up to 20 years of life mainly to the consequences of smoking. Although mental health patients often want to quit and can do so successfully, smoking is rarely addressed in mental health care. Guidance from the National Institute of Health and Care Excellence (NICE) recommends that mental health settings become entirely smokefree, and mental health patients should have access to evidence-based stop smoking treatment.

For many patients, receiving treatment in a smokefree inpatient environment will be a rare experience of abstaining from tobacco. Currently, no strategies to help maintain or achieve a smokefree lifestyle and avoid relapse post-discharge exist, meaning most patients will return to old smoking behaviours within days of discharge.

We have developed the SCEPTRE intervention to support mental health inpatients after discharge to maintain abstinence or positively change their smoking behaviour, building on existing evidence, behaviour change theory, and working closely with service users and mental healthcare professionals. The intervention was tested in a small-scale pilot study to test the research materials and processes, and preliminary acceptability to people with mental illness. Based on these findings, the SCEPTRE intervention has been revised and will be tested in the current feasibility trial.

Who can participate?
Adults who are 18 years or older who were smokers before their stay in a hospital's mental health ward and are interested in either maintaining the positive changes to their smoking behaviour or improving their smoking habits once they leave hospital.

What does the study involve?
A support package has been developed to help people with mental health conditions to maintain the positive changes they have made to their smoking behaviour while in hospital. This package will last for 12 weeks after participants have been discharged and will be delivered by a mental health worker trained to provide personalised support to assist them in meeting their smoking behaviour change goals. All participants in the study will have a random chance of receiving the SCEPTRE support package. This means a computer programme will choose if someone receives the support or their usual care. 'Usual care' might mean receiving advice to quit smoking on discharge, offering a short supply of Nicotine Replacement Therapy (NRT) products (smoking cessation medication), or a referral to a local stop-smoking service. Participants will be asked to complete a questionnaire three months and six months after joining the study. The questionnaires can be completed either by email through a secure link, with a member of the research team in person, or via telephone or video call. The questionnaires will take approximately 30 minutes to complete and will ask participants about their smoking habits, mental and physical health, and the health services they use. If someone reports they have not smoked, they will be asked to provide another sample of their breath so that we can measure the Carbon monoxide (CO) in their body.

What are the possible benefits and risks of participating?
If they are allocated to receive the SCEPTRE support package, participants will benefit through the provision of personalised support to change smoking behaviours following a smokefree stay in a mental health hospital. By positively changing their smoking behaviours, this may have both physical and mental health benefits.

Where is the study run from?
Sheffield Health and Social Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2023 to November 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
329622

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 58805, NIHR200607, IRAS 329622

Study information

Scientific Title
A randomised, controlled feasibility study of the SCEPTRE intervention to support smoking cessation and prevent relapse to tobacco use following a smoke free mental health inpatient stay

Acronym
SCEPTRE Feasibility Trial

Study objectives
The aim of this study is to assess the feasibility and acceptability of a new intervention to support smoking cessation and prevent relapse after a smoke-free mental health inpatient stay.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/10/2023, North West- Greater Manchester West Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8278; gmwest.rec@hra.nhs.uk), ref: 23/NW/0312

Study design

Randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Smoking cessation in persons with mental health disorders

Interventions
Baseline data collection:
Once participant eligibility has been confirmed and consent has been obtained, a baseline visit will be completed to collect all baseline data. The following measures will be collected at baseline:
- Demographic measures (gender, age, marital status, ethnicity, primary mental health diagnosis, smoking status, housing/accommodation status)
- Mental and physical health measures: The nine-item Patient Health Questionnaire depression scale (PHQ-9), the Generalised Anxiety Disorder 7-item scale (GAD-7), and the quality of life scale (EQ-5D-5L), will be included. The frequency of use of health services during the inpatient stay and in the last six months (before hospital admission and during inpatient stay) will also be collected.

Smoking history and behaviour: Smoking history and behaviour prior to admission (including number of cigarettes smoked per day, number of past quit attempts, use of e-cigarettes and NRT); smoking history and behaviour during inpatient stay (including number of cigarettes smoked per day, greatest length of time abstinent during stay, Heaviness of Smoking Index (HSI), Strength of urges to smoke, Motivation to Quit Questionnaire, and use of e-cigarettes and NRT.
Participants will also be asked about their smoking status intention post-discharge.
Participants will be asked to provide a carbon monoxide (CO) reading.

Randomisation:
Following a baseline assessment, randomisation will be undertaken by a member of the Trusts research team using REDCap. The outcome of the allocation will be communicated to the participant where possible in person but may also be communicated by text or telephone call.

Follow up data collection:
Participants will be asked to complete questionnaires at 3 and 6 months post-randomisation. Participants will be asked the same questions as the baseline visit minus the demographic questions. Depending on participant preference, they will be able to complete these via email, in person with a researcher or over the phone/video call.
Participants who self-report that they have not smoked will be asked to provide a carbon monoxide (CO) reading.

Qualitative interviews:
Patient and relative/friend participants will also be invited to take part in short semi-structured interviews at the 3 month follow-up time point to gain a more in-depth understanding of the

feasibility of the study procedures and intervention delivery, as well as the impact of the intervention on the patient participant. Semi-structured interviews will also be conducted with the MTSs to explore their experience and perceptions of delivering the intervention.

Patient and public involvement:
The SCEPTRE PPI group have contributed to the design of both the intervention components, participant study documents, intervention resources, and have provided input to the design of intervention delivery mechanisms and measures.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment and retention measured using screening data and retention rates captured throughout the duration of the study.
2. Compliance with the protocol measured using self-assessment checklists completed by the MTS's and reported protocol deviations throughout the duration of the study.
3. Level of contamination and suitability of randomisation approach measured using qualitative data collected at 3-months post randomisation and quantitative data collected at 3- and 6-months post randomisation from control participants who quit or reduce smoking.
4. Additional qualitative and quantitative measures of acceptability by undertaking semi-structured interviews with control and intervention group participants at 3 months post-randomisation.

Key secondary outcome(s))
Measured using self report (unless otherwise noted):
1. Self-reported 7-day point prevalence abstinence from tobacco validated by exhaled CO <10ppm at 3 and 6 months,
2. Self-reported relapse following discharge from hospital at 3 and 6 months,
3. 1, 2, and 3-month continuous abstinence at 3 months post randomisation,
4. 4, 5, and 6-month continuous abstinence at 6 months post randomisation
5. Tobacco consumption at baseline, 3- and 6-months post-randomisation,
6. Number of quit attempts at baseline, 3 and 6 months,
7. Motivation to quit at baseline 3 and 6 months,
8. Heaviness of Smoking Index at baseline, 3 and 6 months,
9. Use of NRT/e-cigarettes at baseline, 3 and 6 months,
10. Self-efficacy related to smoking cessation at baseline, 3 and 6 months,
11. Change in mental health PHQ-9 at baseline, 3 and 6 months,
12. Change in mental health GAD-7 at baseline, 3 and 6 months,
13. Change in mental health EQ-5D at baseline, 3 and 6 months,
14. Cost of delivering the SCEPTRE intervention and the control condition and feasibility of collecting health economic data measured using a bespoke health resource use questionnaire at 3 and 6 months post-randomisation.

Completion date
27/11/2024

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 10/07/2024:
1. Adults (18 years+) who smoked prior to/during admission on acute NHS mental health wards and express an interest in maintaining abstinence or positively changing their smoking behaviour following discharge
2. Planned discharge within seven to fourteen days to address/accommodation within Trust's catchment area
3. Able to understand and communicate in English
4. Access to a telephone or alternative digital advice to receive post-discharge support
5. Willing and able to provide informed consent
Exclusion criteria:
6. Admitted under the care of older adult, learning disability, psychiatric intensive-care unit or forensic mental health services
7. Patients deemed not clinically appropriate to participate (at clinician discretion)

Previous participant inclusion criteria:
1. Adults aged 18 years and older (no maximum age)
2. Current admission to an acute adult mental health inpatient setting
3. Planned discharge within seven to fourteen days to address/accommodation within the Trust' s catchment area
4. Tobacco smokers at time of admission or at any point after (as patients occasionally still commence smoking after admission) who express an interest in maintaining abstinence (if smokefree at time of assessment) or in positively changing their smoking behaviour following discharge (including cigarette reduction and e-cigarette approaches)
5. Able to understand and communicate in English
6. Access to a telephone or computer/alternative digital device to receive post-discharge support
7. Willing and able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
38

Key exclusion criteria
1. Admitted under the care of older adult, learning disability, psychiatric intensive-care unit (PICU) or forensic mental health services.
2. Patients deemed not clinically appropriate to participate in study (at clinician discretion).

Date of first enrolment

23/01/2024

Date of final enrolment
12/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds and York Partnership NHS Foundation Trust
St. Marys House
St. Marys Road
Leeds
United Kingdom
LS7 3JX

Study participating centre
East London NHS Foundation Trust
Robert Dolan House
9 Alie Street
London
United Kingdom
E1 8DE

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
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United Kingdom
AL10 8YE

Study participating centre
Leicestershire Partnership NHS Trust
Riverside House
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Study participating centre
Derbyshire Healthcare NHS Foundation Trust
Trust Headquarters
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DE22 3LZ

Study participating centre
Oxford Health NHS Foundation Trust
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Warneford Lane
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Sponsor information

Organisation
Sheffield Health and Social Care NHS Foundation Trust

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the Chief Investigator- Elena Ratschen (elena.ratschen@york.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/06/2025	20/06/2025	Yes	No
Participant information sheet	version 1.0	19/10/2023	17/11/2023	No	Yes
Participant information sheet	version 1.2	30/04/2024	11/07/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	05/09/2023	17/11/2023	No	No
Protocol file	version 2.0	30/04/2024	11/07/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes